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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,575	KODADEK, THOMAS J.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *2,6,16-21,24-29 and 31-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-15,22,23 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/23/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-39 are currently pending.

Claims 2, 6, 16-21, 24-29 and 31-39 are withdrawn from further consideration as being drawn to a nonelected invention

Claims 1, 3-5, 7-15, 22-23 and 30 are under consideration.

Election/Restriction

1. Applicant's election, without traverse, of Group I (claims 1-15, 22-26 and 29-30) in the applicant's correspondence dated May 19, 2004 is acknowledged.

2. Accordingly, claims 16-21, 27-28 and 31-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

3. Applicant's response dated May 19, 2004 electing the following species is acknowledged:

a. ICS (Interleukin converting enzyme(ICE) cleavage site epitope) as the "target peptide";

b. Lambda repressor as the "1st DNA binding domain" and "2nd DNA binding domain";

c. LEBP as the "library encoded peptide";

d. Bgal as the "indicator peptide"; and

e. LacZ operator as the "Procaryotic Operator region".

Applicant's election of a "stabilizing interaction" or "3rd peptide" was not required

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a))

4. It is noted that applicant failed to indicate claims readable on the elected invention.

Claims 1, 3-5, 7-15, 22, 23 and 30 read on the election invention, while claims 2, 6, 24-26 and 29 are not readable on the elected invention. Accordingly, claim 2,6, 24-26 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-5, 7-15, 22-23 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step indicating the formation of a "peptide-peptide interaction" and an identification step which are essential in light of the method preamble e.g. "A method for identifying a peptide-peptide interaction".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 1, 3-5, 7-15, 22-23 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al., Nature Biotechnology Vol. 18 (Jan. 2000) pages 71-74.

The present claims are directed to a method for identifying a peptide-peptide interaction comprising:

(a) providing a 1st fusion construct comprising a "target peptide" & a "1st DNA binding domain";

(b) providing a 2nd fusion construction comprising a "library encoded peptide (LEP)" fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region";

(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" comprising an operator operationally linked to a coding region for "one or more indicator polypeptides"; and

(d) determining binding of said complex to said operator region.

The Zhang Nature reference teaches a "method for identifying a peptide-peptide interaction" (e.g. "Screen a peptide library for molecules that bind selectively a target peptide") using a lambda repressor reconstituting assay comprising:

(a) providing a 1st fusion construct comprising a "target peptide" (e.g.NEAYVHGPVRSLN: 13 amino acids corresponding to ICS and ICE substrate: see page 71 of the reference); & a "1st DNA binding domain";

(b) providing a 2nd fusion construct comprising a "library encoded peptide (LEP)" (e.g. Sau3A1 digest of chicken genomic DNA comprising fragments of "5 to about 50 residues") fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region";

(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" (e.g. E.Coli: see page 71, right column) comprising an operator (e.g. LacZ) operationally linked to a coding region for "one or more indicator polypeptides" (e.g.Bgal) (see Fig. 1 of the reference) ; and

(d) determining binding of said complex to said operator region (e.g. see pages 72-73; figures 2-4 e.g. western blots describing target-LEP binding w/n scope of present claims 12-15).

The reference analogously employs a different target e.g. a 13-residue sequence from an internal region of IGF1 prohormone (KPAKSARSVARAQR). See pages 73.

9. Claims 1, 3-5 and 7-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al., Current Biology (3/12/99) Vol. 9: 417-420.

The Zhang Current Biology reference teaches a "method for identifying a peptide-peptide interaction" (e.g. "Screen a peptide library for molecules that bind selectively a target peptide") using a lambda repressor reinstitution assay comprising:
(a) providing a 1st fusion construct comprising a "target peptide" (e.g. a corresponding library peptide); & a "1st DNA binding domain";
(b) providing a 2nd fusion construction comprising a "library encoded peptide (LEP)" fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region";
(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" (e.g. E.Coli) comprising an operator (e.g. LacZ) operationally linked to a coding region for "one or more indicator polypeptides" (e.g.Bgal) (see Fig. 1 of the reference and Table 1) ; and
(d) determining binding of said complex to said operator region (e.g. see table 1).

10. Claims 1, 3-5, 8-11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Jappelli et al. J. Mol. Biology (1996) Vol. 259: 575-578.

Japelli teaches a "method for identifying a peptide-peptide interaction" (e.g. enzyme-protein inhibitor complex: or "protein-protein recognition" or "protein-peptide

interactions: see e.g. page 575, left column) utilizing a lambda repressor reconstitution assay comprising:

(a) providing a 1st fusion construct comprising a "target peptide" (e.g. alpha isoform of the human cAPKc's e.g. amino acids 6-350) & a "1st DNA binding domain" (e.g. amino acids 1-102) (e.g. see page 576, Fig. 1, especially Fig. 1(A));

(b) providing a 2nd fusion construction comprising a "library encoded peptide (LEP)" (e.g. PKI: 20 amino acid: 5-24 and mutants thereof) fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region" (e.g. see Figure 1, especially 1B and page 577, left column: "interaction between the kinase and high affinity peptide inhibitor, which serves to dimerize the repressor");

(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" (e.g. bacterial cell: E.Coli i.e. strain Q537) comprising an operator operationally linked to a coding region for "one or more indicator polypeptides" (e.g.see Table 1 description of E. Coli strain Q537) with fusion "under control of the lac promoter" (e.g. see Fig. 1); and

(d) determining binding of said complex to said operator region elicited by cotransformants expressing receptor fusions being resistant to lamba infection (e.g. see page 577 and Table 1).

The Japelli reference teaches (e.g. page 575 and page 577, left column) the presence of a prokaryotic operator region (e.g. operationally linked to one or more indicator

proteins) and the role of the DNA binding domain's dimerization to effect repressor reconstitution

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3-5, 8-11, 22, 23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jappelli et al. J. Mol. Biology (1996) Vol. 259: 575-578 and Peters et al. US Pat. No. 6,214,561 (3/01: filed 11/97).

Japelli teaches a "method for identifying a peptide-peptide interaction" (e.g. enzyme-protein inhibitor complex: or "protein-protein recognition" or "protein-peptide interactions: see e.g. page 575, left column) utilizing a lambda repressor reconstitution assay comprising:

(a) providing a 1st fusion construct comprising a "target peptide" (e.g. alpha isoform of the human cAPKc's e.g. amino acids 6-350) & a "1st DNA binding domain" (e.g. amino acids 1-102) (e.g. see page 576, Fig. 1, especially Fig. 1(A));

(b) providing a 2nd fusion construction comprising a "library encoded peptide (LEP)" (e.g. PKI: 20 amino acid: 5-24 and mutants thereof) fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region" (e.g. see Figure 1, especially 1B and page 577, left column: "interaction between the kinase and high affinity peptide inhibitor, which serves to dimerize the repressor");

(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" (e.g. bacterial cell: E.Coli i.e. strain Q537) comprising an operator operationally linked to a coding region for "one or more indicator polypeptides" (e.g.see Table 1 description of E. Coli strain Q537) with fusion "under control of the lac promoter" (e.g. see Fig. 1); and

(d) determining binding of said complex to said operator region elicited by cotransformants expressing receptor fusions being resistant to lamba infection (e.g. see page 577 and Table 1).

The Japelli reference teaches (e.g. page 575 and page 577, left column) the presence of a prokaryotic operator region (e.g. operationally linked to one or more indicator

proteins) and the role of the DNA binding domain's dimerization to effect repressor reconstitution upon interaction between the kinase and peptide inhibitor.

Although, the Japelli reference teaches "assessing binding of the target peptide to the library encoded peptide" (as in determining binding e.g. inhibition constants: e.g. see page 577 both columns) the Japelli reference differs from the presently claimed invention (e.g. claim 30) by failing to explicitly teach "assessing binding of the target peptide to the library encoded peptide by use of Western blot, mass spectroscopy (MS) or nuclear magnetic resonance (NMR)".

Peters et al. teach that Western blot (e.g. see col. 1, especially lines 40-50), mass spectroscopy (e.g. MALDI: see col. 2, especially lines 25-30) recpresent "common methods" to screen libraries for determining target/ligand binding. Additionally, the Peters et al. reference teach a preferred NMR technique for determining target/ligand binding. E.g. see col. 3-6; patent claims 1-19.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize routine screening protocols (E.g. western blot/MS/NMR) as taught by the Peters et al. reference for "assessing binding of the target peptide to the library encoded peptides" of the Japelli reference as a matter of design choice with a reasonable expectationof success.

13. Claims 1, 3-5, 7-11, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jappelli et al. J. Mol. Biology (1996) Vol. 259: 575-578 and Watt et al. US Pat. No. 6,610,495 (8/03: filed 1/99 or earlier).

Japelli teaches a "method for identifying a peptide-peptide interaction" (e.g. enzyme-protein inhibitor complex: or "protein-protein recognition" or "protein-peptide interactions: see e.g. page 575, left column) utilizing a lambda repressor reconstitution assay comprising:

(a) providing a 1st fusion construct comprising a "target peptide" (e.g. alpha isoform of the human cAPKc's e.g. amino acids 6-350) & a "1st DNA binding domain" (e.g. amino acids 1-102) (e.g. see page 576, Fig. 1, especially Fig. 1(A));

(b) providing a 2nd fusion construction comprising a "library encoded peptide (LEP)" (e.g. PKI: 20 amino acid: 5-24 and mutants thereof) fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region" (e.g. see Figure 1, especially 1B and page 577, left column: "interaction between the kinase and high affinity peptide inhibitor, which serves to dimerize the repressor");

(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" (e.g. bacterial cell: E.Coli i.e. strain Q537) comprising an operator operationally linked to a coding region for "one or more indicator polypeptides" (e.g.see Table 1 description of E. Coli strain Q537) with fusion "under control of the lac promoter" (e.g. see Fig. 1); and

(d) determining binding of said complex to said operator region elicited by cotransformants expressing receptor fusions being resistant to lamba infection (e.g. see page 577 and Table 1).

The Japelli reference teaches (e.g. page 575 and page 577, left column) the presence of a prokaryotic operator region (e.g. operationally linked to one or more indicator

proteins) and the role of the DNA binding domain's dimerization to effect repressor reconstitution upon interaction between the kinase and peptide inhibitor.

Although, the Japelli reference teaches the utilization of an E. Coli. host with a lac promoter containing an operator operationally linked to "one or more indicator polypeptide" the Japelli reference fails to teach the use of B-gal as an indicator polypeptide in its peptide-peptide lambda repressor reconstitution assay.

However, Watt et al. teach methods for modulating "protein-protein" interactions involving "reconstitution of a functional transcription factor leading to expression of the reporter molecule" (e.g. col. 6) including protein-protein dimerization involving DNA-binding domains (e.g. see col. 7) in which host cell expression preferably employs E. Coli , lac (lacz) promoter and an operator linked to beta-galactosidase as the "preferred reporter molecule" (e.g. see col. 12-13).

Accordingly, one of ordinary skill in the art would be motivated to modify the Japelli reference expression system (e.g E. Coli) to further utilize beta galactosidase as an indicator polypeptide in light of the Watt reference teaching of the preferred use of such an indicator polypeptide in protein-protein DNA binding dimerization assays analogous to the Japelli reference method.

Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Japelli reference E.coli expression system to select beta galactosidase as a reporter molecule in light of the Watt et al. Reference teaching that such a reporter is preferred.

14. Claims 1, 3-5, 8-15, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jappelli et al. J. Mol. Biology (1996) Vol. 259: 575-578.

Japelli teaches a "method for identifying a peptide-peptide interaction" (e.g. enzyme-protein inhibitor complex: or "protein-protein recognition" or "protein-peptide interactions: see e.g. page 575, left column) utilizing a lambda repressor reconstitution assay comprising:

(a) providing a 1st fusion construct comprising a "target peptide" (e.g. alpha isoform of the human cAPKc's e.g. amino acids 6-350) & a "1st DNA binding domain" (e.g. amino acids 1-102) (e.g. see page 576, Fig. 1, especially Fig. 1(A));

(b) providing a 2nd fusion construction comprising a "library encoded peptide (LEP)" (e.g. PKI: 20 amino acid: 5-24 and mutants thereof) fused to a "2nd DNA binding domain" wherein the binding domains work as a complex to facilitate binding of the domains to a "prokaryotic operator region" (e.g. see Figure 1, especially 1B and page 577, left column: "interaction between the kinase and high affinity peptide inhibitor, which serves to dimerize the repressor");

(c) contacting said 1st and 2nd fusion constructs in a "prokaryotic host cell" (e.g. bacterial cell: E.Coli i.e. strain Q537) comprising an operator operationally linked to a coding region for "one or more indicator polypeptides" (e.g.see Table 1 description of E. Coli strain Q537) with fusion "under control of the lac promoter" (e.g. see Fig. 1); and

(d) determining binding of said complex to said operator region elicited by cotransformants expressing receptor fusions being resistant to lamba infection (e.g. see page 577 and Table 1).

The Japelli reference teaches (e.g. page 575 and page 577, left column) the presence of a prokaryotic operator region (e.g. operationally linked to one or more indicator proteins) and the role of the DNA binding domain's dimerization to effect repressor reconstitution

The Japelli reference teaching differs from the presently claimed invention by failing to explicitly teach: "target peptide"/ "LEP binding" ranging from "about $1x10^{-3}$ - about $1X10^{-6}$M" (claim 12); particularly: about $1x10^{-4}$M ; about $1x10^{-5}$M; and about $1x10^{-6}$M (claims 13-15, respectively).

However, the Japelli reference teaches the use of a lamba repressor reconstitution assay to generate lambda infection resistant mutants with binding affinities of:

a. 1.6 x10-9 M (wild type PKI (6-22))

b. 1.74x10-8 M (Tyr 10 peptide analog)

c. 4.25x10-7 (Phe10Ala mutant)

Accordingly, thes mutants differ from the wild type by having 10-100 fold less binding.

The Japelli reference further provides explicit motivation to make a "random peptide library" in order to further screen additional clones for binding in order to discover more phenotypes or to select rare phage resistant variants. See page 577, left to right column.

Accordingly, one of ordinary skill of the art would be motivated to produce "random PKI peptide libraries" comprising hundreds/thousands/millions or more (e.g $\leq$20 different amino acids at each position of a PKI dodecapeptide) infectious resistant

PKI mutants and screen such mutants for binding affinities with a reasonable expectation of achieving one or more mutants containing binding affinities within the scope of the presently claimed invention (e.g. "about $1x10^{-3}$ - about $1X10^{-6}M$" ; about $1x10^{-4}M$; about $1x10^{-5}M$; and about $1x10^{-6}M$); especially in light of the fact that the small sample screened by the reference produced mutants with binding affinities 10-100 times less than the wild-type.

Thus, it would have been obvoius to one of ordinary skill in the art to make and screen "random PKI peptide libraries" as suggested by the Japelli reference and achieve infectious resistant mutants with "target peptide"/ "LEP binding" ranging from "about $1x10^{-3}$ - about $1X10^{-6}M$" with a reasonable expectation of success.

Relevant Prior Art of Record:

1. Lehninger, Biochemistry: The Molecular Basis of Cell Structure and Function (Worth Publishing: 1970) pages 729-736 describing E.coli, repressor/inducer binding at operon regarding beta galactosidase activity. See especially Figures particularly Fig. 32-1 and 32-2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
July 30, 2004